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David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

MAILED

#38

AUG 2 2001

REEXAM UNIT

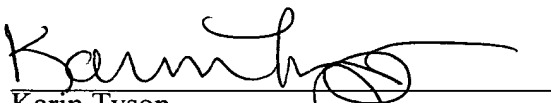
Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 4,738,974 was filed on April 19, 2001, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, NEXIUM™ (esomeprazole magnesium), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act (FFDCA), this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156, if the approval of esomeprazole magnesium is the first permitted use of the product under Section 505 of the FFDCA. It is noted that FDA records reflect that esomeprazole magnesium is a new product, but not a new chemical entity and that FDA considers the product to be a new ester, new salt, or other noncovalent derivative of a previously approved product. Further information is requested. A copy of the relevant page from the Patent and Exclusivity Data Appendix to the Orange Book, the FDA Drug Approvals list, and a document titled NDA Approvals for Calendar Year 2001 are enclosed.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).


Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosures: Copy of application for Patent term extension
Papers from FDA's home page

cc: Leslie Morioka
Patent Department, White & Case
1155 Avenue of the Americas
New York, NY 10036-2787

Enclosure: Papers from FDA's home page

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